



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/931,342 | 08/16/2001 | Brendon Conlan | | 2986 |

7590 06/20/2003
James D. Jacobs, Esq.
Baker & McKenzie
805 Third Avenue
New York, NY 10022

EXAMINER

PHASGE, ARUN S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1753

DATE MAILED: 06/20/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,342

Applicant(s)

CONLAN ET AL.

Examiner

Arun S. Phasge

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/470,823.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendment to the claims filed on 10/23/01 does not comply with the requirements of 37 CFR 1.121 because it requires the cancellation of claims that are not a part of the present specification. Accordingly, the amendment has not been entered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,464,851 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims when read in light of the specification clearly encompass and render obvious the claimed method.

The method of the prior patent disclose the separation of blood protein from a pathogen, including the group presently claimed, comprising the steps of providing a biological liquid with potential pathogens present in an apparatus comprising an anode and a cathode and a separation means, such as the membranes claimed, positioned between said anode and said cathode, applying current between said anode and cathode causing one of said pathogens or said protein to pass said separation means and recovering the protein essentially free of pathogens (see claims 1-36). The reference further discloses the size of the pores (see claim 30). The patent further claims the use of multiple membranes (see claims 10-18).

The reference does not disclose that the separation means is a filtration means, such as ultrafiltration or nanofiltration membrane. The membranes claimed in the prior patent would encompass the presently claimed range. Accordingly, the invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made that the present claims are obvious embodiments of the prior patent, because the prior patent discloses the broad range of materials being treated and membranes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Margolis, WO 94/22904.

Margolis discloses the claimed method and apparatus for the removal of either a pharmaceutically active molecule from a pathogen or a pathogen from a pharmaceutically active molecule in a biological liquids comprising the steps of

Art Unit: 1753

providing a biological liquid, where pathogens are potentially present in an apparatus comprising an anode and a cathode and a separation means, such as the semi-permeable membrane, applying current between the anode and cathode to cause one of said pathogens or pharmaceutically active molecules to pass said separation means and recovering the molecule essentially free of pathogens (see claims 1-12). The reference discloses the selection of different cut-off values for the membranes, which would read upon the claimed membranes and different filtration characteristics (see pages 10-12). The apparatus includes a container for the uptake of said biological liquid (see figure 3).

Therefore, the claims are anticipated.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullon et al. (Mullon), article entitled, "Forced-Flow Electrophoresis of Proteins and Viruses.

Mullon discloses the claimed method and apparatus for the removal of either a pharmaceutically active molecule from a pathogen or a pathogen from a pharmaceutically active molecule in a biological liquids comprising the steps of providing a biological liquid, where pathogens are potentially present in an apparatus comprising an anode and a cathode and a separation means, such as the

semi-permeable membrane, applying current between the anode and cathode to cause one of said pathogens or pharmaceutically active molecules to pass said separation means and recovering the molecule essentially free of pathogens (see pages 124-126). The reference discloses the selection of different cut-off values for the membranes, which would read upon the claimed membranes and different filtration characteristics (see pages 123-126). The apparatus includes a container for the uptake of said biological liquid (see figure 1). The reference further discloses the separation of viruses from protein (see page 134).

Therefore, the claims are anticipated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun S. Phasge whose telephone number is (703) 308-2528. The examiner can normally be reached on MONDAY-THURSDAY, 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X Nguyen can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is

Art Unit: 1753

assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read 'Arun Phasge'. The signature is fluid and cursive, with a large initial 'A' and 'P'.

Arun S. Phasge
Primary Examiner
Art Unit 1753

asp
June 16, 2003